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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,459	08/26/2003	Thomas Yung-Hui Chien	1001.2205101	5094

11050 7590 04/26/2011
SEAGER, TUFTE & WICKHEM, LLC
1221 Nicollet Avenue
Suite 800
Minneapolis, MN 55403

EXAMINER

HOUSTON, ELIZABETH

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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04/26/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/648,459	Applicant(s) CHIEN ET AL.	
	Examiner ELIZABETH HOUSTON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12-21 and 23-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,12-21 and 23-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Prosecution Reopened

1. In view of the Pre-Appeal Brief filed on 12/21/10, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 14 -16, 19, 20 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lau (US 5,421,955) in view of Stack (US 6,264,683).
4. Lau discloses a stent delivery system (see entire reference in particular C6:L35-C7:L2 and note US 5114423 to Kasprzyk incorporated by reference) comprising: [see Fig. 1 of Kasprzyk] an inner tube (14) comprising a proximal end, a distal end, and a lumen (15) extending therebetween, the inner tube being disposed within an outer tube (11) with an annular space (32) disposed therebetween, the distal end of the inner tube further comprising a distal tip (for example 31) a heating element (24) positioned around the inner tube proximal to the distal tip, the outer tube comprising a proximal end (13) and a distal end, the distal end of the outer tube being disposed proximally to the distal tip of the inner tube and defining a distal end diameter (see Fig. 1), the distal end of the outer tube being connected to a balloon (23) which extends between the distal end of

Art Unit: 3731

the outer tube and the distal tip of the inner tube, the balloon overlying the heating element (for example portion 30), wherein the annular space is not in fluid communication with the lumen of the inner tube and an exterior of the balloon, and [see Fig. 1-3 of Lau] an expandable stent (10) positioned around the balloon and disposed between the distal end of the outer tube and the distal tip. Regarding claim 4: the balloon is also connected to the distal tip of the inner tube (see Kasprzyk, Figure 1). Lau further discloses the steps of inserting the stent delivery system with the stent in the unexpanded form, into the vasculature system and to a desired position, and heating the stent to expand the stent and causing it to adhere to the vasculature system at the desired position (CC4:L53-C5:L6 and C6:L44-56); deflating the balloon, and withdrawing the inner and outer tubes and balloon from the vasculature system (it is inherent that the balloon would be deflated and the catheter withdrawn from the vasculature after the stent is delivered to its desired site). Regarding claim 15: during the heating of the stent, the balloon is heated and partially inflated (C6:L41-52). Regarding claim 16, during the inserting step, the balloon and stent are cooled (relative to the warm temperature applied to the stent during deployment at the site of the stenosis). Regarding claim 19: the heating is performed using a heating element. Regarding claim 27: Lau discloses supplying current to the heating element to expand the stent and causing it to adhere to the vasculature at the desired position (Lau C6:L41-52 and Kasprzyk C5:L(45-57)).

5. Lau does not explicitly disclose that the edge diameter of the tapered distal tip of the inner tube and the distal end diameter of the outer tube are equal to or greater than

Art Unit: 3731

a maximum outer diameter of the stent in an unexpanded form. However, Stack discloses a stent delivery device with an inner tube having a tapered distal tip (20) with a proximal edge diameter and an outer tube defining a distal end diameter, wherein both diameters are equal to or greater than a maximum outer diameter of the stent in an unexpanded form (Figs. 1-4) in order to prevent slippage of the stent and prevent the stent from contacting the vessel wall during delivery (C1:L42-67). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate retainers on the deliver device of Lashinski to achieve the same advantages.

6. With respect to claim 20, Lau/Kasprzyk does not disclose the heating element is a coil with a power line and a return line encased in a layer of insulating material (in reference to the embodiment of Figure 1). However, Kasprzyk discloses another embodiment (Figure 4) that incorporates the use of a coil heating element (50, 51) for supplying heat to the immediate area surrounding a balloon (C6:L16-22). The heating element is connected to a power supply (33) via a power line and a return line which are insulated (C4:L52-C5:L25). It would have been obvious to one having ordinary skill in the art at the time of the invention to substitute a heating element that is a coil in place of the conductive coaxial cable. The substitution of one known element for another would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution would have yielded predictable results, namely, a manner of heating the stent for expansion.

Art Unit: 3731

7. Claims 1, 3-9, 12, 13, 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lau (US 5,421,955) in view of Stack (US 6,264,683) and further in view of Lashinski (6,579,305).

8. Lau discloses the invention substantially as claimed as stated above. Lau discloses a stent that is transitioned by a change in temperature but the stent is plastic rather than shape memory. Lau discloses a stent made of shape memory, but the shape memory stent is transitioned by a change in stress rather than a change in temperature (C6:L35-C7:L2). Lashinski discloses wherein the stent is formed of a stent material having a shape memory transition temperature lower than an elevated temperature produced by the heating element so that the stent expands in response to the heating provided by the heating element (C1:L43-62; C4:L43-54). Doing so provides more control over expansion and eliminates the need for an outer sheath thereby reducing the overall profile and improving the ability to navigate tortuous vessels (C2:L33-61). Lashinski further discloses: regarding claims 6 and 25: the stent comprises nitinol (C1:L45). Regarding claim 7 and 26: the stent is a self-expanding stent (C4:L51 where the stent is shape memory nitinol and expanded by influence of heat). In light of the teachings of Lau and Lashinski, it would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a heat transition stent in place of a stress induced transition stent to achieve the more expansion control and a reduced profile. Regarding claims 5 and 24: both Lau (C4:L33-36) and Lashinski (C4:L2) disclose the stent is crimped onto the balloon. Regarding claim 8, both Lau (4:L25-32) and Lashinski disclose the balloon is made of elastomeric material.

Art Unit: 3731

9. With respect to claims 3, 12 and 13, Lau/Kasprzyk does not disclose the heating element is a coil with a power line and a return line encased in a layer of insulating material (in reference to the embodiment of Figure 1). However, Kasprzyk discloses another embodiment (Figure 4) that incorporates the use of a coil heating element (50, 51) for supplying heat to the immediate area surrounding a balloon (C6:L16-22). The heating element is connected to a power supply (33) via a power line and a return line which are insulated (C4:L52-C5:L25). It would have been obvious to one having ordinary skill in the art at the time of the invention to substitute a heating element that is a coil in place of the conductive coaxial cable. The substitution of one known element for another would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution would have yielded predictable results, namely, a manner of heating the stent for expansion.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lau (US 5,421,955) in view of Stack (US 6,264,683) and Lashinski (6,579,305) and further in view of Fischell (US 5,976,153).

11. Modified Lau discloses the invention substantially as claimed as stated above but does not disclose a radiopaque marker. However, Fischell teaches a distal radiopaque marker (13d) disposed immediately proximal to the distal tip and a proximal radiopaque marker (13p) which is disposed immediately distal to the distal end of the outer tube (for example as seen in configuration of Fig. 3). It would have been obvious to one having

Art Unit: 3731

ordinary skill in the art at the time of the invention to incorporate radiopaque markers in order to better track the delivery device and more accurately place the stent.

12. Claim 17, 18, 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lau (US 5,421,955) in view of Stack (US 2,264,683) as applied to claims 14, 16 and 27 above, and further in view of Rabkin (US 6,676,692)

13. Modified Lau discloses the invention substantially as claimed as stated above but does not disclose the use of a using warm saline solution for heating the stent.

However, Rabkin discloses that it is well known in the art to use a warm saline solution delivered into the balloon in order to achieve the transition temperature of the stent for expansion. It would have been obvious to one having ordinary skill in the art at the time of the invention to substitute the use of a warm saline solution in place of a conductive cable or coil in order to effect the transition of the stent.

The substitution of one known element for another would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution would have yielded predictable results, namely, a way of achieving the transition temperature of the stent for expansion. KSR, 550 U.S. at, 82 USPQ2d at 1396.

14. Modified Lau discloses the invention substantially as claimed as stated above but does not disclose the use of cool saline solution to cool the stent and balloon during delivery. However Rabkin discloses that it is well known in the art to use a cooling fluid during delivery to ensure that the stent does not expand prematurely (C18:L13-29). It

Art Unit: 3731

would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate this same feature to achieve the same advantage.

15. Claims 21 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lau (US 5,421,955) in view of Stack (US 6,264,683) as applied to claims 19 and 27 above and further in view of Healy (US 6607553).

16. Modified Lau does not further disclose a thermocouple located on the distal end of the inner tube for monitoring the temperature. However Healy discloses the use of a thermocouple for monitoring that the temperature of the stent is high enough to transition the stent without being too high too damage the tissue (C8:L52-67). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a thermocouple for the same advantage. Regarding the location of the thermocouple it would have been obvious to one having ordinary skill in the art at the time the invention was made relocate the thermocouple to location that provides the most efficient feedback for its use since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 10:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth Houston/
Examiner, Art Unit 3731
04/20/11